SEP 23 2002

510(k) Summary of Safety and Effectiveness
OrthoGuard AB Antimicrobial Sleeve

K022676

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	August 7, 2002
Contact Person:	Janet Johnson Green Director, Regulatory Affairs
Proprietary Name:	OrthoGuard AB Antimicrobial Sleeve
Common Name:	Antimicrobial Pin/Wire Sleeve
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Product Code and Panel Code:	JEC / NJA – Orthopedics/87

Predicate Device / Substantial Equivalence Information
The OrthoGuard AB Antimicrobial Wire Sleeve is similar to the OrthoGuard AB Antimicribial Pin Sleeves included in 510(k) K012193. The following properties of the wire sleeve are the same as for the pin sleeves currently offered: intended use, material and coating formulation, manufacturing and coating method, labeling, and sterilization method. While the OrthoGuard AB Antimicrobial Wire Sleeve is not identical to the predicates, any differences that may exist do not significantly affect the safety or effectiveness. Therefore, the OrthoGuard AB Antimicrobial Wire Sleeve is substantially equivalent to the predicate devices.

Device Description
The OrthoGuard AB Antimicrobial Sleeve consists of polyurethane tubing coated on the inner and outer surfaces with an antimicrobial coating of gentamicin complexed with lauryl sulfate in a matrix of nitrocellulose and polyurethane.

Intended Use
The OrthoGuard AB Antimicrobial Sleeve is intended to be used as an accessory surrounding orthopaedic pins and wires during external fixation of bones. The OrthoGuard AB Antimicrobial Sleeve is indicated to inhibit bacterial colonization on the pin/wire.

Technological and Performance Characteristics
The technological and performance characteristics of the OrthoGuard AB Antimicrobial Sleeve were compared to the predicate device. The results of this comparison support the safety and effectiveness of the device and substantial equivalence to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Ms. Janet Johnson Green
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K022676
Trade/Device Name: OrthoGuard AB Antimicrobial Sleeve
Regulation Number: 21 CFR §888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JEC and NJA
Dated: August 8, 2002
Received: August 12, 2002

Dear Ms. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022676

OrthoGuard AB Antimicrobial Sleeve
Indications Statement

The OrthoGuard AB Antimicrobial Sleeve is intended to be used as an accessory surrounding orthopaedic pins and wires during external fixation of bones. The OrthoGuard AB Antimicrobial Sleeve is indicated to inhibit bacterial colonization on the pine/wire.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022676